

that suggest, within the context in which they are presented, that a relationship exists between wine, alcohol, or any substance found within the wine, and a disease or health-related condition.

(iii) *Health-related directional statement* is a type of health-related statement that directs or refers consumers to a third party or other source for information regarding the effects on health of wine or alcohol consumption.

(2) *Rules for labeling*—(i) *Health-related statements*. In general, labels may not contain any health-related statement that is untrue in any particular or tends to create a misleading impression as to the effects on health of alcohol consumption. TTB will evaluate such statements on a case-by-case basis and may require as part of the health-related statement a disclaimer or some other qualifying statement to dispel any misleading impression conveyed by the health-related statement.

(ii) *Specific health claims*. (A) TTB will consult with the Food and Drug Administration (FDA), as needed, on the use of a specific health claim on a wine label. If FDA determines that the use of such a labeling claim is a drug claim that is not in compliance with the requirements of the Federal Food, Drug, and Cosmetic Act, TTB will not approve the use of that specific health claim on a wine label.

(B) TTB will approve the use of a specific health claim on a wine label only if the claim is truthful and adequately substantiated by scientific or medical evidence; sufficiently detailed and qualified with respect to the categories of individuals to whom the claim applies; adequately discloses the health risks associated with both moderate and heavier levels of alcohol consumption; and outlines the categories of individuals for whom any levels of alcohol consumption may cause health risks. This information must appear as part of the specific health claim.

(iii) *Health-related directional statements*. A statement that directs consumers to a third party or other source for information regarding the effects on health of wine or alcohol consumption is presumed misleading unless it—

(A) Directs consumers in a neutral or other non-misleading manner to a third party or other source for balanced information regarding the effects on health of wine or alcohol consumption; and

(B)(1) Includes as part of the health-related directional statement the following disclaimer: “This statement should not encourage you to drink or to increase your alcohol consumption for health reasons;” or

(2) Includes as part of the health-related directional statement some other qualifying statement that the appropriate TTB officer finds is sufficient to dispel any misleading

impression conveyed by the health-related directional statement.

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## Subpart E—Requirements for Withdrawal of Wine From Customs Custody

### § 4.40 Label approval and release.

(a) *Certificate of label approval*. No imported beverage wine in containers shall be released from U.S. Customs custody for consumption unless there is deposited with the appropriate Customs officer at the port of entry the original or a photostatic copy of an approved certificate of label approval, ATF Form 5100.31.

(b) If the original or photostatic copy of ATF Form 5100.31 has been approved, the brand or lot of imported wine bearing labels identical with those shown thereon may be released from U.S. Customs custody.

(c) *Relabeling*. Imported wine in U.S. Customs custody which is not labeled in conformity with certificates of label approval issued by the appropriate ATF officer must be relabeled prior to release under the supervision and direction of Customs officers of the port at which the wine is located.

(d) *Cross reference*. For procedures regarding the issuance, denial, and revocation of certificates of label approval, as well as appeal procedures, see part 13 of this chapter.

[T.D. ATF-66, 45 FR 40546, June 13, 1980, as amended by T.D. ATF-94, 46 FR 55095, Nov. 6, 1981; T.D. ATF-242, 51 FR 39525, Oct. 29, 1986; T.D. ATF-359, 59 FR 42160, Aug. 17, 1994; T.D. ATF-406, 64 FR 2128, Jan. 13, 1999]

### § 4.45 Certificates of origin and identity.

Imported wine shall not be released from customs custody for consumption unless the invoice is accompanied by a certificate of origin issued by a duly authorized official of the appropriate foreign government, if the issuance of such certificates with respect to such wine has been authorized by the foreign government concerned, certifying as to the identity of the wine and that the wine has been produced in compliance with the laws of the respective